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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,819	08/03/2001	Roland Buelow	14750	8351

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/921,819

Applicant(s)

BUELOW ET AL.

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 and 31-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 August 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to the restriction requirement received on 10/27/03 has been entered. Applicant's election with traverse of the subject matter of Group III, claims 13-30, is acknowledged. Claims 1-60 are pending in the instant application. Of these, claims 1-12, and 31-60 have been withdrawn from prosecution as being drawn to an invention non-elected with traverse on 10/27/03. Claims 13-30 are therefore under examination in the instant application. An action on the merits follows.

Restriction/Election

As noted above, the applicant has elected with traverse the subject matter of Group III, claims 13-30. The traversal is based on applicant's argument that the subject matter of Groups IV and V should be examined along with Group III because these claims are closely related and the prior art search of these inventions would be overlapping. Therefore, the applicant argues that it would not be an undue burden on the examiner to examine all these inventions together. Applicant's arguments have not been found persuasive. The previous office action stated that vectors of invention III have substantially different structural, chemical, and biological properties than the transgenic animals and B cells of invention IV-V, are made using different techniques, and can be used for substantially different purposes. In particular, please note that the vectors of invention III can be used for purposes other than making a transgenic

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animal, such as the use of the vectors to transfect cells *in vitro*, or the use of the vectors to generate probes for hybridization assays. In addition, the methods of making transgenic animals of invention IV require substantial additional search based on the techniques involved which are not used to make the vectors of invention III. Likewise, B cells derived from a transgenic animal are made using techniques which are not used to make the vectors of invention III. Thus, the search for the vectors of group III is not co-extensive with the search for inventions IV and V which would require substantial additional search and consideration. Therefore, for reasons of record, these inventions are distinct and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and different search requirements. As such, the restriction for examination purposes as indicated is maintained.

Information Disclosure Statement

The information disclosure statements filed on 3/9/02 and 3/20/03 fail to comply with 37 CFR 1.98(a)(3) because they do not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. The 1449s have been placed in the application file, but the information referred to which has been lined through by the examiner has not been considered. References not considered by the examiner include publications written in german and japanese for which no translation or concise explanation of the relevance for these documents has been provided.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13-30 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2002/0028488 (3/7/02), hereafter referred to as Singh et al. The applicant claims transgenic vectors comprising a humanized Ig locus which comprises a portion of an Ig locus of a non-human mammal and at least one human Ig gene segment in unrearranged, partially rearranged or fully rearranged configuration, wherein the humanized locus is capable of undergoing gene conversion in a non-human animal. The claims further recite wherein the non-human animal is a chicken, wherein the humanized locus is a heavy chain locus which comprises at least one V gene segment, one D gene segment, one J gene segment, and a human heavy chain constant region gene segment, preferably the human C γ gene segment. Other claims recite wherein the humanized locus is a light chain locus which comprises at least one V gene segment, one D gene segment, and a human light chain constant region gene segment, preferably the human kappa or lambda constant gene segments. The applicant also claims wherein the vector comprises about 10-100 V gene segments, where the segments are selected from V gene segments at the 3' V-region of the non-human animal and human V gene segments.

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Singh et al. teaches transgenic vectors, preferably YAC vectors, which comprise a fragment of the human Ig heavy or light chain loci in unrearranged configuration comprising at least one V region heavy chain gene segment, all of the D region heavy chain gene segments and J region segments and at least one heavy chain constant region gene, or comprising at least one V region kappa or lambda light chain gene segment, all of the J region light chain segments and either the kappa or lambda light chain constant region gene segment, flanked by regions of homology to the chicken immunoglobulin locus (Singh et al., columns 10-11, and Figures 2A and 2B). Please note that the chicken is an animal which generates antibody diversity primarily through gene conversion. Singh et al. also teaches that the flanking regions of homology to the chicken immunoglobulin locus preferably include regions of the chicken variable region sequences including one or more chicken V_H the 5' end and chicken constant region sequences at the 3' end such that the human immunoglobulin loci is inserted into via homologous recombination into the chicken variable region loci (Singh et al., column 11, columns 21-22, and Figure 3). The resulting vectors may have at least 10 V gene segments wherein at least one of the V gene segments is a chicken V gene segments and at least one is a human V gene segment. Thus, by teaching all the limitations of the claims as written, Singh et al. anticipates the instant invention as claimed.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be

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reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 872-9306.

Please note that the United States Patent and Trademark Office will begin to move to the new campus in Alexandria, Virginia, in December 2003. The examiners of Art Unit 1632 will be moving in January 2004. As of January 13, 2004, this examiner's phone number will be (571) 272-0737, and that of the examiner's supervisor will be (571) 272-0734.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

A handwritten signature in cursive script, appearing to read 'Anne M. Wehbé', with a long horizontal stroke extending to the right.